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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/051,443 04/10/98 WIDERSTROM

C 06275/124001

EXAMINER

QM12/0328

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ART UNIT

PAPER NUMBER

3761
DATE MAILED:

03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/051,443

Applicant(s)

Widerstrom

Examiner

Joseph Weiss

Group Art Unit

3761



☒ Responsive to communication(s) filed on Apr 10, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-5 and 7-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5 and 7-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

This application has been examined upon a full entry of Preliminary Amendment A filed, 10 April 1998 & a partial entry of Preliminary Amendment B filed 19 Aug 1999. The language of Claim 10 in Pre-AMDT B conflicts with that of the present claim 10 and therefore it and the newly added dependent claims 11 & 12 are not entered and will not be examined in this office action. An action based upon an examination of the merits of the remainder of the instant application's claims follows.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claims 2-4, lines 2 of claims 2 & 3 recitation of "said container" is unclear since two different types of containers were previously set forth & it is unclear which set applicant is referring to, this rendering the claims indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by

Goettenauer et al (DE 4400084 A1).

In regards to claim 1, Goettenauer discloses an inhaler (33) comprising an inhalation channel (21); a first container (1) for containing medicament; a first release means (3/28) to release medicament into the channel; a subsidiary container (1) for containing medicament; a subsidiary release means (3/28) to release the subsidiary container's medicament into the inhalation channel; wherein the two release means are independently operable which results in one or more of each containers being operated to release medicament into the channel at the same time to vary dosage and which is fully capable of having different fractions or relative ratios of medicament contained within the different medicament containers.

In regards to claim 2, Goettenauer discloses the containers as being integral with the inhaler.

In regards to claim 3, Goettenauer discloses the containers as being depressions in at least one wall of the inhalation channel with the release means comprising films that seal the depressions.

In regards to claim 5, Goettenauer discloses the medicament used as being in a powdered form.

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In regards to claim 7, Gottenauer discloses the inhaler as having at least 2 subsidiary containers which are fully capable of containing at least 2 subsidiary doses which are a predetermined fraction of a first dose in a first container.

In regards to claim 8, Gottenauer is fully capable of having subsidiary doses with different fractions of a first dose.

It is noted that applicant is currently not positively claiming the medicament doses contained within the containers, therefore such limitations are not being drawn to the invention (an inhaler). Furthermore the operation/function and environment limitations within which the device is placed to achieve an intended result do not produce structural differences, and therefore given minimal patentable weight and not distinguishing over the prior art since it is fully capable of performing such operation/functional limitations, is designed for such an environment and thus able to achieve the intended results set forth. In order for such limitations to be distinguishing they first must be positively claimed as part of the invention and/or the operational/functional and environment limitations must impart a distinction upon the invention wherein the prior art would not be capable of also meeting.

Also, please note that 1/1 is a fraction.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Goettenauer et al.

In regards to claim 4, Goettenauer discloses the release means as comprising one or more elongated members (Fig 8) attached to or integral with said films (by dint of container film 36 which is integral with cover film 3) and with free ends which may be pushed by a user in order to remove the films from their respective depressions, thereby releasing medicament contained within the respective depressions, but applicant arranges its release means to a user my pull instead of push, i.e. a reversal of known parts for a known purpose.

It is noted that applicant's specification does not set forth this reversal of parts, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

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In regards to method claims 9-10, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claim 1.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-5 & 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting (Common Assignee) as being unpatentable over claims 1-19 of U.S. Patent No. 5533505. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth an inhaler having an inhalation channel with a container formed a depression in a wall of the inhaler that is integral with the container for containing a dose of medicament with a film release means that is pulled by a user for the release of medicament, however the claims of the instant application set forth the use of multiple containers, whereas US 5533505 discloses the use of only one such container, i.e. the duplication of a known part for a known purpose.

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It is noted that applicant's specification does not set forth the duplication of a known part for known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

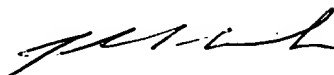
Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6105574, 5918594, 5797392, 5673686, 5660169, 5239991

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.


J. Weiss

March 22, 2001


John G. Weiss
Supervisory Patent Examiner
Group 3700